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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

ROCHESTER DRUG CO-OPERATIVE, INC., on behalf of itself and all others similarly situated,

Plaintiff,

v.

UNIMED PHARMACEUTICALS, INC.; SOLVAY PHARMACEUTICALS, INC.; WATSON PHARMACEUTICALS, INC.; PAR PHARMACEUTICALS, INC., and PADDOCK LABORATORIES, INC.,

Defendants.

EDCV09-0226 SGL (OPx)

Case No.

CLASS ACTION COMPLAINT

JURY TRIAL DEMAND

CLASS ACTION COMPLAINT

Plaintiff Rochester Drug Co-Operative, Inc. ("RDC" or "Plaintiff"), by and through its undersigned attorneys, brings this action on behalf of itself and all others similarly situated, against defendants Unimed Pharmaceuticals, Inc. and Solvay Pharmaceuticals, Inc. (collectively, "Unimed"); Watson Pharmaceuticals, Inc. ("Watson"); Paddock Laboratories, Inc. ("Paddock"); and Par Pharmaceuticals, Inc. ("Par") (collectively, "Defendants"). Plaintiff makes the following allegations based upon personal knowledge as to those matters relating to itself and upon information and belief as to all other matters.

I. NATURE OF THE ACTION

1. This is a civil antitrust action seeking to recover overcharges (trebled) arising out of Defendants' unlawful delay and exclusion of generic competition from the market for the drug sold under the brand name Androgel and its A-rated generic equivalents (collectively, the "Drug"). Androgel is a branded drug marketed by Unimed for topical use as a testosterone replacement therapy ("TRT") for males with a deficiency or absence of endogenous testosterone.

2. As detailed below, Defendants conspired to restrain trade, and engaged in a scheme to monopolize the U.S. market for the drug sold under the brand name Androgel and its A-rated generic equivalents, by substantially delaying the onset of generic competition of A-rated generic versions of Androgel. Among other aspects of its exclusionary scheme, Unimed entered into agreements with its prospective generic competitors Par, Paddock, and Watson (collectively the "Generic Defendants"), whereby Unimed agreed in September 2006 to pay the Generic Defendants tens of millions of dollars, as well as provide other compensation, in exchange for agreements by the Generic Defendants not to sell their respective A-rated generic versions of Androgel for nearly a decade. Specifically, through these agreements, Watson, the first Abbreviated New Drug Application filer, agreed to stay off the market until 2015, and the other Generic Defendants, until 2016.

3. As of 2006, Androgel was Unimed's top-selling pharmaceutical product, with U.S. sales in 2006 of over $300 million and in 2007 of over $400 million. Defendants' conspiracy delayed generic entry of A-rated generic versions of Androgel, thereby overcharging purchasers, including members of the direct purchaser Class defined below, by many millions of dollars.

4. All Defendants realized that United States Patent No. 6,503,894 (the "'894 patent"), which Unimed listed in the U.S. Food & Drug Administration's ("FDA") "Orange Book" as covering Androgel, was weak and susceptible to attack as being invalid or unenforceable. Additionally, the Generic Defendants asserted that their respective formulations of the Drug did not infringe on the '894 patent.

5. A-rated generic versions of brand name drugs contain the same active ingredient, and are found by the FDA to be just as safe and effective, as their brand name counterparts. The only material difference between A-rated generics and corresponding brand name drugs to which they are A-rated (sometimes hereinafter referred to as the "reference listed drug" or "RLD") is their price – A-rated generics are typically at least 30% less expensive than their corresponding RLD when there is a single A-rated generic competitor; this discount typically increases to 50-80% (or more) when there are multiple A-rated generic competitors on the market for the same RLD. As a result, A-rated generics constitute both: (a) an opportunity for drug purchasers to obtain enormous cost savings; and (b) a serious threat to the monopoly power and profits of the manufacturer of the RLD facing potential generic competition. Indeed, A-rated generic versions of brand name drugs typically take 80% or more of the sales of a drug molecule from the brand name product within a year (or less) of generic entry.

6. Defendants' agreements are anticompetitive because Defendants apportioned to themselves the surplus from competitive generic entry that would have and should have accrued to purchasers of Androgel, including members of the proposed Class.

7. The dollar value of a drug's sales typically decreases dramatically once it faces A-rated generic entry, because the drug is increasingly being purchased in the form of the less-expensive A-rated generic rather than the brand. For example, a branded drug with annual sales of $400 million prior to A-rated generic entry can have the dollar value of its sales–even if the total number of prescriptions for the drug product remains the same–drop to under $100 million (RLD and A-rated generic combined) following A-rated generic entry, because prescriptions for the RLD will rapidly be automatically substituted by pharmacists, who will instead dispense the A-rated generic. While this drop allows purchasers to buy the A-rated generic at a fraction of the cost of the RLD, and thus save money, it presents a strong financial incentive for branded and generic manufacturers to collude and split the (in this example) $300 million surplus (savings) that would have otherwise gone to purchasers. By delaying generic entry, brand and generic manufacturers are able to capture these excess profits and split the much higher dollar value of the RLD's sales. That is precisely what Defendants did here.

8. In order to maintain supra-competitive pricing, Unimed and the Generic Defendants agreed to delay generic entry until 2015 and 2016 and share in the supracompetitive profits earned unlawfully during that period of delay. Unimed's multi-million dollar payments to the Generic Defendants compensated them for agreeing to delay their market entry. Unimed itself knew that it would reap excess profits during that period of unlawful delay. Defendants' anticompetitive agreements, therefore, were in the financial interest of each of the Defendants, but harmed drug purchasers, consumers, competition and consumer welfare.

9. Acutely aware of these economic realities of the pharmaceutical industry, Unimed engineered a scheme whereby it would, *inter alia*: (a) make significant payments to the Generic Defendants in exchange for their agreements to refrain from selling their less expensive A-rated generic versions of Androgel until either 2015 or 2016 (*i.e.*, for nearly a decade after their 2006 agreements); and (b)

disguise these "exclusion payments" as payments ostensibly for: (i) licensing and/or co-promotion of Androgel (to Watson and Par); and/or (ii) back-up manufacturing of Androgel (to Par). Defendants intentionally concealed the true purpose and nature of these exclusion payments in an attempt to shield their exclusionary agreements from antitrust scrutiny.

10. Absent the illegal agreements not to compete with the Generic Defendants, generic competition for the Drug would have commenced at or near the time of the settlement agreements in September 2006 (and, at all events, substantially earlier than the 2015 and 2016 dates provided for in the settlement agreements with the Generic Defendants). Had there been free and fair competition in the market for the Drug, Plaintiff and other direct purchasers of Androgel would have paid less for the Drug than they paid because of Defendants' illegal acts to delay generic competition.

11. Defendants, though their illegal scheme: (1) illegally maintained Unimed's monopoly power with respect to the Drug in the United States; (2) fixed, raised, maintained, and/or stabilized prices for the Drug at supra-competitive levels; and (3) overcharged Plaintiff and other direct purchasers of Androgel by millions of dollars by delaying competition from cheaper A-rated generic versions of Androgel.

12. Defendants' "exclusion payment" agreements constitute horizontal market allocation agreements, which are *per se* violations of § 1 of the Sherman Act, and in the alternative, are anticompetitive under the Rule of Reason. Defendants' conduct also constitutes a conspiracy to restrain trade, in violation of §1 of the Sherman Act.

13. Similarly, as alleged in more detail below, Defendants violated § 2 of the Sherman Act through their scheme to improperly maintain and extend Unimed's monopoly power by foreclosing or delaying competition from lower-priced A-rated generic versions of Androgel.

14. Unimed willfully maintained monopoly power with respect to the Drug

through willfully exclusionary conduct, as distinguished from growth or development as a consequence of a legally obtained valid patent, other legally obtained market exclusivity, a superior product, business acumen or historical accident.

II. JURISDICTION AND VENUE

15. This Complaint is filed, and these proceedings are instituted, under Section 4 of the Clayton Act, 15 U.S.C. § 15, to recover threefold damages and the costs of suit and reasonable attorneys' fees, for the injuries sustained by Plaintiff and members of the Class of direct purchasers of Androgel from Unimed resulting from the violation by the Defendants, as hereinafter alleged, of §§ 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2. The jurisdiction of this Court is based upon 28 U.S.C. §§ 1331 and 1337(a), and 15 U.S.C. § 15.

16. Defendants transact business within this district, and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this district. Venue, therefore, is appropriate within this district under 15 U.S.C. § 22, and 28 U.S.C. § 1391(b) and (c).

III. THE PARTIES

17. Plaintiff Rochester Drug Co-Operative, Inc. ("RDC" or "Plaintiff") is a pharmaceutical wholesaler located at 50 Jet View Drive, Rochester, New York, 14624. During the relevant period, Plaintiff purchased Androgel directly from Unimed Pharmaceuticals, Inc. and/or Solvay Pharmaceuticals, Inc., and was injured as a result of Defendants' anti-competitive conduct alleged herein.

18. Defendant Solvay Pharmaceuticals, Inc. ("Solvay") is a Georgia corporation with its principal place of business in Marietta, Georgia. Solvay is the U.S. subsidiary of Solvay Pharmaceuticals. Together with its wholly owned subsidiary Defendant Unimed Pharmaceuticals, Inc., Solvay develops, manufactures, and markets pharmaceuticals and related products, including Androgel, in the United States. Defendant Solvay itself negotiated and/or approved

Unimed's relevant anticompetitive agreements concerning Androgel, the filing and prosecution of the patent cases against Par, Paddock and Watson, and has a financial interest in Androgel. In the twelve months ending December 31, 2007, Solvay's U.S. net revenues included over $400 million from U.S. sales of Androgel.

19. Defendant Unimed Pharmaceuticals, Inc. is a wholly owned subsidiary of Solvay. Unimed Pharmaceuticals, Inc. develops, manufactures, and markets pharmaceuticals and related products, including Androgel, in the United States. Unimed Pharmaceuticals, Inc. focuses on developing and marketing drugs in with multiple indications in the therapeutic areas of cardiology, men's health (urology and endocrinology) and certain infectious diseases.

20. Defendant Par is a Delaware corporation with its principal place of business in Woodcliff Lake, New Jersey. Par principally develops, manufactures and markets generic versions of brand name drugs. In the twelve months ending December 31, 2007, Par had total revenues of approximately $770 million.

21. Defendant Paddock is a privately-held pharmaceutical company located in Minneapolis, Minnesota. Paddock principally develops, manufactures and markets generic versions of brand name drugs.

22. Defendant Watson is a Nevada corporation with its principal place of business in Corona, California. Watson principally develops, manufactures and markets generic versions of brand name drugs. In the twelve months ending December 31, 2007, Watson had net revenues of approximately $2.5 billion.

IV. CLASS ACTION ALLEGATIONS

23. Plaintiff brings this action on behalf of itself and, under Rule 23 of the Federal Rules of Civil Procedure, as representative of a Class defined as follows:

> All persons or entities in the United States who purchased Androgel in any form directly from Unimed at any time during the period from September 13, 2006, until the

anticompetitive effects of Defendants' conduct cease (the "Class").

Excluded from the Class are Defendants, and their officers, directors, management, employees, subsidiaries, or affiliates, and all governmental entities.

24. Members of the Class are so numerous that joinder is impracticable. Plaintiff believes the Class numbers at least in the hundreds. Further, the Class is readily identifiable from information and records in Defendants' possession.

25. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff and all members of the Class were damaged by the same wrongful conduct by Defendants, *i.e.*, it paid artificially inflated prices for the Drug and was deprived of the benefits of competition from cheaper A-rated generic versions of Androgel as a result of Defendants' wrongful conduct.

26. Plaintiff will fairly and adequately protect and represent the interests of the Class. Plaintiff's interests are coincident with, and not antagonistic to, those of the Class.

27. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, and have particular experience with class action antitrust litigation in the pharmaceutical industry.

28. Questions of law and fact common to the members of the Class predominate over questions, if any, that may affect only individual Class members because Defendants have acted on grounds generally applicable to the entire Class. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

29. Questions of law and fact common to the Class include:

a. whether Defendants' agreements constitute illegal market allocation agreements;

b. whether Unimed unlawfully maintained monopoly power in the market for the Drug by delaying generic entry;

c. whether direct proof of Unimed's monopoly power is available, and if available, whether it is sufficient to prove Unimed's monopoly power without the need to also define a relevant market;

d. to the extent a relevant market or markets must be defined, what that definition is or those definitions are;

e. whether the activities of Defendants as alleged herein have substantially affected interstate commerce; and

f. whether, and to what extent, Defendants' conduct caused antitrust injury in the nature of overcharges.

30. Class action treatment is a superior method for the fair and efficient adjudication of the controversy, in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that it might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

31. Plaintiff knows of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

V. FACTUAL ALLEGATIONS

A. The Regulatory Structure Pursuant to Which Generic Substitutes for Brand Name Drugs Are Approved

32. Under the Federal Food, Drug, and Cosmetics Act (21 U.S.C. §§ 301-392), manufacturers who create a new, pioneer drug must obtain the approval of the FDA to sell the new drug by filing a New Drug Application ("NDA"). An NDA must include submission of specific data concerning the safety and effectiveness of

the drug, as well as any information on applicable patents.

33. In 1984, Congress amended the Food, Drug and Cosmetics Act with the enactment of the Hatch-Waxman amendments, called the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman").

34. Hatch-Waxman simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file a lengthy and costly NDA in order to obtain FDA approval. Instead, the FDA provides an expedited review process by which generic manufacturers may file an Abbreviated New Drug Application ("ANDA").

35. The ANDA relies on the scientific findings of safety and effectiveness included by the brand name drug manufacturer in the original NDA. The ANDA filer must demonstrate to the FDA that the generic drug it proposes to market is pharmaceutically equivalent and bioequivalent to the reference listed (*i.e.*, brand name) drug.

36. As a counter-balance to this abbreviated process for bioequivalent generic drugs, Hatch-Waxman streamlined the process for a brand name manufacturer to enforce its patents against infringement by generic manufacturers, and provided that, under certain conditions (as detailed below), the FDA could not grant a generic manufacturer final approval to market or sell a generic version of the brand name drug for up to 30 months following institution of patent infringement litigation by the brand name drug manufacturer against would-be generic competitors.

37. When the FDA approves a brand name manufacturer's NDA, the FDA publishes any compound patents which (according to the brand name manufacturer) claim the approved drug in a publication entitled the "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the "Orange Book." 21 U.S.C. § 355(j)(7)(A)(iii). In the case of method of use patents, the FDA lists in the

Orange Book any patents which (according to the brand name manufacturer) claim the approved drug for its approved method of use. In listing patents in the Orange Book, the FDA merely performs a ministerial act. The FDA does not check the facts supplied to it by the brand name manufacturer, but trusts that the manufacturer will be truthful. After the NDA is approved, the brand name manufacturer may list other new patents in the Orange Book as related to the NDA, if the brand name manufacturer similarly certifies, *inter alia*, that the new patents claim either the approved drug (for compound patents) or that the patents claim the approved drug for approved methods of use (for method-of-use patents).

38. To obtain FDA approval of an ANDA (and thus the right to sell a generic version of a brand name drug), a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any patents listed in the Orange Book. Under Hatch-Waxman, a generic manufacturer's ANDA must contain one of four certifications:

i. that no patent for the brand name drug has been filed with the FDA (a "Paragraph I certification");

ii. that the patent for the brand name drug has expired (a "Paragraph II certification");

iii. that the patent for the brand name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); or

iv. that the patent for the brand name drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

21 U.S.C. § 355(j)(2)(A)(vii).

39. If a generic manufacturer files only paragraph I, II, or III certifications, then it is able to take advantage of the expedited Hatch-Waxman approval process, and the FDA must act on the application within 180 days of receipt, unless both the

FDA and the applicant agree to extend the deadline. 21 U.S.C. § 355(j)(5)(A).

40. If a generic manufacturer files a Paragraph IV certification claiming that a patent listed in the Orange Book is invalid or will not be infringed, a brand name manufacturer has an opportunity to delay the final FDA approval of the ANDA and the sale of the competing generic drug on the market. When a generic drug manufacturer files a Paragraph IV certification with its ANDA, the generic manufacturer must promptly give notice of its certification to both the NDA-holder and the owner of the patent(s) at issue. If the NDA-holder initiates a patent infringement action against the ANDA filer within 45 days of receiving the Paragraph IV certification, then the FDA may not grant final approval to the ANDA until the earlier of either: (a) 30 months from the date the ANDA is filed; or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). Thus, by listing a patent in the Orange Book and filing a suit within 45 days of receiving a Paragraph IV certification regarding the listed patent, a brand name drug manufacturer may delay when the generic drug is finally approved by the FDA, and when generic competition to the brand name drug enters the market. During the pendency of the 30 month stay, the FDA may grant "tentative approval" to an ANDA applicant if the FDA determines that the ANDA would otherwise qualify for final approval but for the stay.

41. Because of the FDA rules alleged above, brand name manufacturers have an incentive to: (a) list patents in the Orange Book, even if such patents are not eligible for listing; and (b) then sue any generic competitor that files an ANDA with paragraph IV certifications, even if such competitor's product does not actually infringe the listed patent(s), in order to delay final FDA approval of an ANDA for up to 30 months. In addition, prior to a recent change in the Hatch-Waxman regulations, brand companies could, and did, bring multiple infringement suits (based on multiple patents listed in the Orange Book) against a single ANDA,

thereby obtaining independent 30-months stays associated with each suit. This practice was curtailed by a change in FDA regulations mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which, due to repeated abuses by brand manufacturers of the type described here, limited brand manufacturers to a single stay per ANDA. *See* 21 C.F.R. §§ 314.52, 314.95, 314.107(b)(3)(i)(A).

B. Generic Versions of Brand Name Drugs are Significantly Less Expensive, and Take Significant Sales Directly From the Corresponding Brand Name Versions

42. Typically, A-rated generic versions of brand name drugs are priced significantly below their corresponding RLD. A 1998 Congressional Budget Office Report estimates that in 1994 alone, purchasers saved $8 to $10 billion on prescriptions at retail pharmacies by purchasing generic drugs instead of the RLD. A 2004 FDA study calculates that patients could reduce the daily costs of their medications by more than 50 percent by purchasing generic drugs when available.

43. Significant purchaser savings typically result when generic companies successfully challenge patents and enter prior to patent expiration. For example, a generic company's successful challenge invalidating a patent covering the antidepressant drug Prozac resulted in generic entry 2.5 years before patent expiry and about $2.5 billion in estimated savings to drug purchasers. Another successful challenge invalidating patents covering the cancer drug Taxol resulted in generic entry over 11 years before patent expiry and estimated savings to purchasers of more than $3.5 billion.

44. Because of the price differentials, and other institutional features of the pharmaceutical market, A-rated generic versions of drugs are rapidly and substantially substituted for their RLD counterparts. In every state, pharmacists are permitted (and, in most states, required) to substitute an A-rated generic product for a brand name product unless the doctor has indicated that the prescription for the

brand name product must be dispensed as written. As additional A-rated generic manufacturers enter the market, prices for A-rated generic versions of an RLD predictably decrease even further because of competition among the generic manufacturers, and the loss of sales volume by the brand name drug to the corresponding A-rated generics accelerates.

45. An "A" rating is particularly significant to a generic manufacturer because, under the statutory regime enacted by both Congress (*i.e.*, Hatch-Waxman) and most state legislatures (which enacted Drug Product Selection, or DPS laws), pharmacists may substitute an A-rated generic version of a drug for the brand name without seeking or obtaining permission from the prescribing doctor (unless the prescription is denominated "Dispense as Written," or DAW). Indeed, both Congress and the state legislatures have actively encouraged automatic generic substitution at the pharmacy counter because of their recognition that the economics of the pharmaceutical industry prevents generic manufacturers from simultaneously: (a) engaging in the type of heavy promotion or "detailing" typically done by brand name manufacturers; and (b) providing the enormous cost savings to purchasers and consumers generated by generic drugs.

46. A-rated generic competition enables all members of the proposed Class to: (a) purchase generic versions of the drug at substantially lower prices; and/or (b) purchase the RLD at a reduced price. However, until an A-rated generic manufacturer enters the market, there is no bioequivalent generic drug which competes with the brand name drug, and therefore, the brand name manufacturer can continue to charge supracompetitive prices profitably without losing all or a substantial portion of its brand name sales. Consequently, brand name drug manufacturers have a strong interest to use the tactics alleged in this Complaint to delay the introduction of generic competition.

C. Solvay's Androgel Patent

47. Androgel is a brand name drug marketed by Unimed and indicated for

replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone. Androgel is indicated to treat those with primary hypogonadism and hypogonadotropic hypogonadism. Low testosterone is often associated with advancing age, certain cancers, diabetes, and HIV/AIDS, among other conditions, and can result in fatigue, muscle loss, and erectile dysfunction.

48. Testosterone itself is unpatented, and patents covering the synthesis of artificial testosterone expired decades ago. The Androgel patent is for the use of a gel formulation containing testosterone and certain other ingredients in specified amounts. Androgel allows for topical application and controlled release of testosterone into the bloodstream.

49. In August 1995, Solvay licensed the U.S. rights to the testosterone gel formulation used for Androgel from the Belgian pharmaceutical company Besins Healthcare, S.A. (together with its affiliates, "Besins"), which had developed the formulation. At the same time, Besins agreed to supply Solvay with Androgel after the FDA approved the product for sale. By 2007, Solvay's U.S. sales of Androgel exceeded $400 million. Solvay sells Androgel at prices far above what Solvay pays Besins for the drug. Even accounting for other direct expenses Solvay allocates to selling and marketing Androgel, the drug is highly profitable for Solvay.

50. In August 2005, Solvay's and Besins's employees applied for a U.S. patent for Androgel.

51. As described in a report by the United States Government Accountability Office, patent examiners are generally expected to process an average of 87 patent applications per year and have time quotas of a total of 19 hours to process each application from its filing through its final acceptance or rejection. These time quotas are reinforced by examiners' bonus compensation, which is largely tied to the number of applications processed to completion. The patent application process is an *ex parte* process in which patent examiners rely upon the information and candor of applicants. The vast majority of all patent

applications are ultimately granted.

52. In prosecuting the patent application relating to Androgel, Solvay submitted to the patent examiner multiple disclosure statements identifying more than 400 articles and patents discussing previous testosterone and hormone therapies, together with copies of each of these hundreds of articles and patents in multiple notebooks, comprising more than three feet of materials for the examiner to attempt to review. In addition, Solvay filed more than 240 additional pages of papers, responses, amendments, and declarations.

53. The patent Solvay prosecuted issued on January 7, 2003 as Patent No. 286,503,894 (the "formulation patent"). Five months later, Solvay requested that the Patent and Trademark Office "correct" many claims of the formulation patent by inserting a scientific term that would substantially reduce the amount of one of the components of the formulation and change the coverage of the claims. Nonetheless, Solvay represented that this "correction" would not "alter the substance of the patent in any way that would necessitate reevaluation by an Examiner." The certificate of correction issued some six months later.

54. The formulation patent expires in August 2020. Solvay recently received regulatory exclusivity from the FDA based on pediatric studies that would provide Solvay with an additional six months of exclusivity beyond the expiration of its patent, through February 2021.

D. Generic Challengers

55. The FDA approved Unimed's NDA No. 021015 for Androgel in 2000, and Unimed began selling Androgel shortly thereafter.

56. Unimed listed the '894 patent in the FDA's Orange Book, asserting that the patent was valid and its claims covered the formulation of Androgel.

57. In early 2003, Watson filed with the FDA ANDA No. 76-737, for approval of Watson's A-rated generic equivalent to Androgel. Watson's ANDA contained a Paragraph IV certification that the '894 patent was invalid,

unenforceable, and/or not infringed by its ANDA. Watson notified Unimed on July 8, 2003 that Watson had filed an ANDA containing a Paragraph IV certification that the '894 patent was invalid, unenforceable, and/or not infringed by Watson' ANDA.

58. In or about January 2006, Defendant Watson received final approval from the FDA to market its A-rated generic version of Androgel, and was awarded 180 days of marketing exclusivity for being the first to file an ANDA containing a Paragraph IV certification.

59. In early 2003, Defendant Paddock filed with the FDA ANDA No. 76-744, for approval of Paddock's A-rated generic equivalent to Androgel. Paddock's ANDA contained a Paragraph IV certification that the '894 patent was invalid, unenforceable, and/or not infringed by its ANDA. Paddock notified Unimed that Paddock had filed an ANDA containing a Paragraph IV certification that the '894 patent was invalid, unenforceable, and/or not infringed by Paddock's ANDA.

60. In July 2003, Defendants Paddock and Par entered into a licensing agreement whereby Par would sell in the United States the generic version of Androgel that Paddock would manufacture.

61. Defendant Paddock's ANDA was tentatively approved on October 27, 2004.

62. Par's CEO told investment analysts in February 2006 that if generic Androgel did not launch in 2006, it "should certainly hit in 2007."

63. In September 2006, Defendant Par announced that it purchased all rights to Defendant Paddock's ANDA for generic Androgel.

E. Defendants' Wrongful Scheme to Delay Generic Competition

64. Following Watson's 2003 ANDA filing and Paragraph IV certification, in August 2003, Unimed sued Watson for infringement of the '894 patent. No dispositive motions were filed in the underlying '894 patent litigation until late 2005.

65. Following Paddock's 2003 ANDA filing and Paragraph IV certification, in August 2003, Unimed sued Paddock for infringement of the '894 patent.

66. Unimed knew that Hatch-Waxman's automatic 30-month stay would protect Androgel from facing generic competition until early 2006, and had little incentive to settle before then.

67. Defendants reached their anticompetitive agreements in 2006, following the expiry of the 30-month stay and the FDA's final approval of Watson's ANDA, and before any dispositive motions in the underlying '894 patent case were ruled upon.

68. On September 13, 2006, Solvay, Besins, and Watson entered written agreements to settle their patent litigation. Under the parties' agreement, Watson agreed to refrain from marketing generic Androgel until August 31, 2015, or earlier if another generic company launched a generic version of Androgel before that date.

69. Unimed agreed to pay Paddock and Par $60 million for Paddock and Par's agreement to delay market entry of their A-rated generic version of Androgel. As a Besins executive wrote in an email, a "backup manufacturer strategy [was] a partial way to compensate Parr [sic] for not entering the market."

70. Unimed also agreed to pay Watson for its agreement to delay market entry. Watson's 180-day exclusivity period meant that Watson effectively could block later generic entrants by delaying its own market entry. Therefore, Watson was in a more advantageous position than Par, and the amount of Unimed's payment to Watson—which amount has not been disclosed (though the *fact* of the payment to Watson has been acknowledged by Watson)—likely exceeded the $60 million that Unimed paid to Par.

71. The amount of Unimed's payment to Watson also had to be substantial enough to compensate Watson for the risk posed to Watson by Solvay's planned new version of Androgel that threatened to destroy the market for the Drug and

make Watson's generic Androgel product far less valuable. Branded pharmaceutical companies sometimes employ the introduction of a "line extension," or a new branded product that is related to but slightly different from an existing product, to preserve sales of a branded franchise in the face of imminent generic competition. Under this strategy, the brand company launches the "line extension" and then encourages switching from the old version to the new line extended version that is not immediately susceptible to erosion from the entry of a generic.

72. In the case of Androgel, Solvay plans to develop and market a testosterone gel containing 1.62% testosterone - more than the 1% testosterone contained in Androgel - that would allow patients to achieve similar therapeutic benefits with less volume of gel. Solvay plans to shift sales from Androgel to its new low volume product before 2015, in part because generic versions of Androgel would not be automatically substitutable for Solvay's new branded product. Watson accepted Solvay's 2015 generic entry date even though a line extension product could have a severe negative impact on its potential sales of any generic Androgel product well before 2015. Watson would not have accepted the 2015 generic entry date in light of these risks, absent Solvay's substantial sharing of Androgel profits with Watson during this period. That payment was made in exchange for Watson's agreement to delay entry of its generic Androgel.

73. In total, Unimed likely paid well over $100 million in total to the Generic Defendants to compensate them for agreeing to delay entry.

74. Perhaps aware that exclusion payments like those described above are *per se* illegal, Defendants touted the payments in their agreements as fees for, *inter alia*, co-promotion and back-up manufacturing. These offered rationales were merely pretextual, and meant to obscure the fact that Defendants agreed to horizontally allocate the market for the Drug, and that the payments were Defendants' mechanism for transferring from Unimed to the Generic Defendants

some of the supracompetitive profits that would be earned by Unimed during the period of delay. The co-promotion, back-up manufacturing, and other pretextual rationales for the payments were of little or no real value to Unimed, and in any event were worth far less than the tens or hundreds of millions of dollars Unimed paid to the Generic Defendants pursuant to the agreements.

75. The anticompetitive agreements between the Defendants were neither examined in-depth nor approved by any governmental antitrust authority. Indeed, since news of Defendants' anticompetitive agreements has become public, the Federal Trade Commission and the Attorney General for the State of California have filed suit in this Court challenging Defendants' agreements as anticompetitive under, *e.g.*, Sections 1 and 2 of the Sherman Act.

76. Given Defendants' collective demonstrated interest in settling the patent litigation and avoiding ultimate adjudication of the patent issues, had Defendants been barred from settling the patent actions with illegal payments from the brand to the generic company, they would have instead agreed to settle the various patent cases in a precompetitive fashion, allowing generics to enter by September 2006 with licenses from Unimed, and at all events, earlier than under the agreements at issue, thus saving Plaintiff and members of the Class millions of dollars.

F. Solvay's Patent Was Unlikely to Prevent Generic Competition to Androgel

77. Watson and Par/Paddock developed evidence during Solvay's patent suits that their generic products did not infringe Solvay's patent and that the patent was invalid and/or unenforceable.

78. Watson and Par/Paddock argued that their products fell outside the limited scope of the patent claims – *e.g.*, because their products contained different ingredients, and ingredients in different amounts.

79. Watson and Par/Paddock also argued that the formulation patent was invalid. Among other things, these firms developed evidence that:

- The patent was invalid under 35 U.S.C. § 102(b) for prior commercial sale or public use of the patented invention, in that Besins offered the invention for sale to Solvay in 1995 - a fact that Solvay and Besins withheld from the Patent and Trademark Office.
- The patent was invalid as obvious under 35 U.S.C. § 103 because the gel formulations and related methods covered by the patent were obvious variations of existing products and methods.
- Many of the patent claims were invalid under 35 U.S.C. § 112 for failure to meet the "written description" requirement.

80. Watson argued that the patent was unenforceable because Solvay and Besins did not disclose their 1995 commercial supply agreement to the patent examiner when they applied for the formulation patent. The generic firms also argued that the certificate of correction that changed the scope of some of the patent claims was invalid and/or did not apply to the pending litigation, which was filed before the certificate of correction issued. By late 2005, Watson and Par/Paddock had filed motions for summary judgment on two of these issues, and addressed others in claim construction briefing and expert reports. Solvay and Besins bore the burden of proving that Watson and Par/Paddock each infringed the formulation patent - in other words, that the generic products were within the scope of the patent claims. Solvay and Besins had not met their burden when the litigation ended in settlements.

81. Solvay and Besins were unlikely to prevent generic entry through their patent lawsuits. To do so, Solvay and Besins had to prove infringement by both Watson and Par/Paddock, and also had to defeat each of the generics' invalidity and unenforceability arguments. If either Watson or Par/Paddock had prevailed on any one of these issues, Solvay's formulation patent would not have prevented generic entry. Sovay and Besins recognized the weakness of their patent claims as evidenced by their willingness to pay the Generic Defendants tens of millions of

dollars to refrain from entering the market rather than seeking injunctive relief from the Court.

82. Once Watson received final FDA approval for its generic product in January 2006, Watson had the ability to launch its generic version of AndroGel unless Solvay was able to satisfy the relevant burdens to obtain a preliminary injunction in the patent case to prevent Watson's launch.

G. Effect on Interstate Commerce

83. At all material times, Androgel, sold by Defendant Unimed, was shipped across state lines and sold to customers located outside its state of manufacture.

84. During the relevant time period, in connection with the purchase and sale of Androgel, monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

85. During the relevant time period, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. The activities of Defendants, as charged in this Complaint, were within the flow of, and have substantially affected, interstate commerce.

H. Monopoly Power

86. Through the anticompetitive conduct alleged herein, Unimed was able to profitably charge supracompetitive prices for Androgel without losing substantial sales, and thus, by definition, maintained monopoly power with respect to the Drug in the United States.

87. To the extent that Plaintiff is required legally to prove monopoly power circumstantially by first defining a relevant product market, the relevant product market is the Drug, *i.e.*, Androgel, and A-rated bioequivalent versions of Androgel. There are no reasonable economic substitutes for Androgel other than A-rated

generic versions of Androgel. Other testosterone drugs are not close enough economic substitutes to prevent Unimed from profitably maintaining prices for the Drug above the competitive level that would be reached upon market entry of an A-rated generic version of Androgel. Substantial barriers to entry exist in the market for the Drug, including the need to conduct expensive clinical trials and obtain FDA approval.

88. For the entire period relevant to this case, Unimed has been able to profitably maintain the price of Androgel well above competitive levels without losing substantial sales.

89. For the entire period relevant to this case, Unimed had the power to control prices of, and exclude competition to, the Drug.

90. For the entire period relevant to this case, Unimed has enjoyed abnormally high profit margins with respect to Androgel.

91. Androgel exhibits low cross-price elasticity of demand with non-Androgel drugs, but would exhibit high cross-price elasticity of demand with A-rated generic versions of Androgel were it not for the conduct complained of herein.

92. By raising or maintaining the price for Androgel a small but significant, nontransitory amount relative to other drugs, Unimed would not lose substantial sales to those other drugs.

93. The relevant geographic market is the United States and its territories.

94. Unimed's market share in the relevant market is and was 100% at all times relevant to this complaint.

95. Defendants' actions are part of, and in furtherance of, the illegal restraint of trade and monopolization alleged herein, were authorized, ordered or done by Defendants' officers, agents, employees or representatives while actively engaged in the management of Defendants' affairs.

96. Defendants' illegal acts to prevent the introduction and/or dissemination

into the U.S. marketplace of any A-rated generic versions of Androgel resulted in Plaintiff and members of the Class paying more than they would have paid for the Drug absent Defendants' illegal conduct.

I. Effects on Competition and Damages to Plaintiff and Class

97. Defendants' exclusionary conduct has delayed or prevented the sale of A-rated generics to Androgel in the United States, and unlawfully enabled Defendants to sell the Drug at artificially inflated prices. But for Defendants' illegal conduct, generic competitors would have been able to successfully market A-rated generic versions of Androgel beginning in September 2006, and additional generic competitors would have entered the market thereafter.

98. If manufacturers of A-rated generic versions of Androgel had entered the marketplace and effectively competed with Defendants, as set forth above, Plaintiff and other members of the Class would have substituted those lower-priced A-rated generic versions for the higher-priced brand name Androgel for some or all of their requirements for the Drug, and/or would have received a lower price (and/or discounts) on some or all of their remaining Androgel purchases.

99. During the relevant period, Plaintiff and other members of the Class purchased substantial amounts of Androgel directly from Unimed. As a result of Defendants' illegal conduct alleged herein, Plaintiff and other members of the Class paid artificially inflated prices for the Drug. Plaintiff and the other Class members paid prices the Drug that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein. As a consequence, Plaintiff and other members of the Class have sustained substantial damage to their business and property in the form of overcharges.

COUNT I

Restraint of Trade In Violation of Section 1 of the Sherman Act And Conspiracy to Restrain Trade, Against All Defendants

100. Plaintiff repeats and incorporates by reference the allegations of ¶¶ 1-99 above.

101. Beginning in or about September 2006, Unimed and each of the Generic Defendants engaged in continuing illegal contracts, combinations and conspiracies in restraint of trade, the purpose and effect of which was to: (a) allocate all sales of the Drug in the United States to Unimed; (b) prevent the sale of the Drug in the United States, thereby protecting Androgel from any generic competition; and (c) fix the price at which direct purchasers would pay for the Drug at the higher, branded price.

102. By entering into these conspiracies, Defendants have unlawfully conspired in restraint of trade and committed a violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. Defendants' agreements are horizontal market allocation and price-fixing agreements between actual or potential competitors, and thus are *per se* violations of Section 1. In the alternative, Defendants' agreements are unreasonable restraints of trade in violation of Section 1, when viewed under a "quick look" or "rule of reason" modes of analysis.

103. Plaintiff and the members of the Class have been injured in their business and property by reason of Defendants' unlawful contract, combination and conspiracy. Plaintiff and the Class members have paid more on their purchases of the Drug than they would have paid absent Defendants' illegal conduct.

104. As a result of Defendants' illegal conduct, Plaintiff and the Class paid more than they would have paid for the Drug. But for Defendants' illegal conduct, competitors would have begun marketing generic versions of Androgel likely in September 2006.

105. If manufacturers of generic versions of the Drug entered the market and competed with Unimed, Plaintiff and other Class members would have substituted lower-priced generic versions of the Drug for the higher-priced brand name Androgel for some or all of their requirements, and/or would have received lower prices on some or all of their remaining Androgel purchases.

106. During the relevant period, Plaintiff and the other Class members purchased substantial amounts of Androgel directly from Unimed. As a result of Defendants' illegal conduct alleged herein, Plaintiff and the other Class members paid artificially inflated prices for the Drug.

COUNT II

Monopolization in Violation of Section 2 of the Sherman Act Against Unimed

107. Plaintiff repeats, and incorporates by reference, the allegations above in ¶¶ 1-106 above.

108. Unimed used various willful and exclusionary means as part of a scheme described herein to improperly maintain and extend monopoly power with respect to the Drug.

109. The goal, purpose and/or effect of Unimed's scheme was to prevent, delay, and/or minimize the success of the entry of A-rated generic versions of the Drug which would have sold at prices significantly below Unimed's prices for Androgel, effectively causing the average market price of the Drug to decline dramatically.

110. The goal, purpose and/or effect of Unimed's scheme was to maintain and extend Unimed's monopoly power with respect to the Drug. Unimed's illegal scheme to prevent, delay, and/or minimize the success of the introduction into the United States marketplace of any generic version of Androgel enabled Unimed to continue charging supra-competitive prices for the Drug without a substantial loss of sales.

111. As a result of Unimed's illegal conduct, Plaintiff and the Class paid substantially more than they would have paid for the Drug. But for Unimed's illegal conduct, competitors would have begun marketing generic versions of Androgel in or about September 2006.

112. During the relevant period, Plaintiff and the other Class members purchased substantial amounts of Androgel directly from Unimed. As a result of Defendants' illegal conduct alleged herein, Plaintiff and the other Class members paid artificially inflated prices for the Drug.

113. Unimed's scheme was in the aggregate an act of monopolization undertaken with the specific intent to maintain and enhance its monopoly power with respect to the Drug in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

COUNT III

Conspiracy to Monopolize In Violation of Section 2 of the Sherman Act Against All Defendants

114. Plaintiff repeats, and incorporates by reference, the allegations in ¶¶ 1-113 above.

115. As detailed above, the Generic Defendants conspired with Unimed with the specific intent to enhance Unimed's monopoly power with respect to the Drug by, *inter alia*, knowingly and intentionally agreeing to keep their A-rated generic versions off the market for nearly a decade in exchange for substantial cash payments. All Defendants committed at least one overt act in furtherance of the conspiracy, which affected interstate commerce.

116. During the relevant period, Plaintiff and the other Class members purchased substantial amounts of Androgel directly from Unimed. As a result of Defendants' illegal conduct alleged herein, Plaintiff and the other Class members paid artificially inflated prices for the Drug. Plaintiff and all of the other Class members paid prices the Drug that were substantially greater than the prices that

they would have paid absent the illegal conduct alleged herein.

VI. DEMAND FOR JURY

117. Plaintiff demands trial by jury on all issues so triable.

VII. REQUEST FOR RELIEF

WHEREFORE, Plaintiff, on behalf of itself and the proposed Class, respectfully request that:

(i) The Court determine that this action may be maintained as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure, and direct that reasonable notice of this action, as provided by Rule 23(c)(2) of the Federal Rules of Procedure, be given to the Class;

(ii) The acts alleged herein be adjudged and decreed to be an unlawful restraint of trade in violation of Section 1 of the Sherman Act; and willful acts of monopolization in violation of Section 2 of the Sherman Act;

(iii) Each member of the Class recover three-fold the damages determined to have been sustained by each of them, and that joint and several judgment be entered against Defendants in favor of the Class;

(iv) Plaintiff and the Class recover their costs of suit, including reasonable attorneys' fees as provided by law; and

(v) The Class be granted such other, further and different relief as the nature of the case may require or as may be determined to be just, equitable, and proper by this Court.

Dated: February 3, 2009

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